Amendment
Attornev Docket No. S63.2B-9867-US01

## Remarks

This Amendment is in response to the Office Action dated **December 18, 2003**. In the Office Action claims 11-13, 35-37, 39 and 40 were rejected under 35 USC 112, 2<sup>nd</sup> paragraph. Claims 1, 7, 9, 10, and 38 were rejected under 35 USC 102(b) as being anticipated by EP 1034751 to Mitsudou et al. Claims 30, 33, 34, and 44 are rejected under 35 USC 102(e) as being anticipated by US 6,258,117 to Camrud et al. Claims 1-4, 6-10, 14, 15, 41, and 42 were rejected under 35 USC 103(a) as being unpatentable over Camrud et al in view of US 5,234, 456 to Silvestrini. Claims 11-13 were rejected under 35 USC 103(a) as being unpatentable over Camrud et al in view of US 5,234, 456 to Silvestrini as applied to claims 1-4, 6-10, 14, 15, 41, and 42 above, and further in view of US 5,591,223 to Lock et al. Claims 35-37 were rejected under 35 USC 103(a) as being unpatentable over Camrud et al in view of US 5,591,223 to Lock et al. Claims 39 and 40 were rejected under 35 USC 103(a) as being unpatentable over Mitsudou et al in view of US 5,591,223 to Lock et al. Claim 45 was rejected under 35 USC 103(a) as being unpatentable over Mitsudou et al in view of US 5,591,223 to Lock et al. Claims 1, 11-13, and 35-40 have been amended. No new matter has been added. Applicants address the rejections under heading consistent with the paragraph numbering of the Office Action.

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In the Office Action claims 11-13, 35-37, 39 and 40 were rejected under 35 USC 112, 2<sup>nd</sup> paragraph. The limitation "radially and/or axially" was said to be indefinite. Applicants have amended these claims and believes the rejection for indefiniteness is overcome.

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Claims 1, 7, 9, 10, and 38 were rejected under 35 USC 102(b) as being anticipated by EP 1034751 to Mitsudou et al. Applicants points out that the Mitsoduo reference does not teach the limitation of a stent that self-expands upon breaking of the at least one frangible restraining member. Rather the Mitsudou reference teaches the use of stents which are balloon expandable (see, for example, paragraph 12 of column 2). The only stent materials mentioned are those listed in paragraph 0068 which are biocompatible and balloon expandable. For at least this reason, claim 1 overcomes the anticipation rejection and is believed to be in condition for

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allowance. Claims 7, 9, and 10 are allowable for at least the reason that they are dependent on claim 1 which is believed to be in condition for allowance.

Claim 38 has been amended to recite that at least a portion of the stent is constructed and arranged to self-expand upon breaking of the at least one temporary strut. As the Mitsudou reference does not teach a stent designed to self-expand, claim 38 is patentable for at least the reason given above for the patentability of claim 1.

Applicants respectfully request that the 102(b) rejection of claims 1, 7, 9, 10, and 38 be withdrawn.

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Claims 30, 33, 34, and 44 are rejected under 35 USC 102(e) as being anticipated by US 6,258,117 to Camrud et al. The Camrud reference does not suggest or teach all of the limitations of claim 30. Camrud does not teach that at least a portion of the stent is capable of self-expanding upon breaking of a frangible restraining member. In as much as Camrud teaches breaking of portions of the stent, the breaking results in increasing axial flexibility or in disconnecting the stent sections from one another (e.g. col. 7, lines 23-25) to provide a plurality of individual, unconnected stents. There is no disclosure that the breaking results in allowing at least a portion of the stent to self-expand as taught in instant claim 30.

In addition, claim 30 recites "a frangible restraining member disposed about at least a portion of the tubular body". The breakable portions of Camrud are not disposed about the tubular body. Rather, they are disposed between the sections of the tubular body.

For at least these reasons, claim 30 overcomes the anticipation rejection and is in condition for allowance. Claims 33 and 34 are allowable for at least the reason that they claim dependence on an allowable base claim. Claim 44 is at least allowable for the reason that it claims as an element the stent in claim 30; as claim 30 is believed to be allowable and not anticipated by Camrud, claim 44 is also not anticipated by Camrud.

Applicants respectfully request that the 102(e) rejection of claims 30, 33, 34, and 44 be withdrawn.

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Claims 1-4, 6-10, 14, 15, 41, and 42 were rejected under 35 USC 103(a) as being unpatentable over Camrud et al in view of US 5,234,456 to Silvestrini. The Office Action acknowledges that Camrud does not disclose a non-woven tubular element having a plurality of openings. In addition, Applicants assert that Camrud also does not disclose that at least a portion of the stent is capable of self-expanding upon breaking of the breakable member as addressed above.

These missing limitations are not provided by Silvestrini. Silvestrini does not teach self expansion after the breakage of frangible members. As this limitation is not taught or suggested in either Camrud or Silvestrini an obviousness rejection is inappropriate. Applicants respectfully request that the 35 USC 103(a) obviousness rejection of claims 1-4, 6-10, 14, 15, 41, and 42 be withdrawn.

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Claims 11-13 were rejected under 35 USC 103(a) as being unpatentable over Camrud et al in view of US 5,234, 456 to Silvestrini as applied to claims 1-4, 6-10, 14, 15, 41, and 42 above, and further in view of US 5,591,223 to Lock et al. Lock does not provide the missing limitations of independent claim 1 addressed above under heading 8. Amended independent claim 1 recites in part a non-woven tubular element comprising a plurality of interconnected members which form at least one continuous pathway which extends all the way around the longitudinal axis, the stent further comprising at least one frangible restraining member. In contrast, Lock is a sleeve stent with a clam shell like configuration and does not have interconnected members which form at least one continuous pathway which extend around the longitudinal axis. Thus, claim 1 is believed to be patentable. Claims 11-13 are patentable for at least the reason that they are dependent upon an allowable base claim.

Applicants respectfully request that the 35 USC 103(a) obviousness rejection of claims 11-13 be withdrawn.

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Claims 35-37 were rejected under 35 USC 103(a) as being unpatentable over

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Camrud et al in view of US 5,591,223 to Lock et al. Claims 35-37 claim dependence on claim 30. Camrud nor Lock teach or suggest "interconnected members which form at least one continuous pathway which extends around the longitudinal axis, the stent further comprising at least one frangible restraining member disposed about at least a portion of the tubular body and restraining at least two interconnected members from self-expansion" as recited in amended claim 30.

As stated under heading 6, Camrud does not teach that at least a portion of the stent is capable of self-expanding upon breaking of a frangible restraining member. In as much as Camrud teaches breaking of portions of the stent, the breaking results in increasing axial flexibility or in disconnecting the stent sections from one another to provide a plurality of individual, unconnected stents. There is no disclosure that the breaking results in allowing at least a portion of the stent to self-expand as taught in instant claim 30. Frangible members within each individual tubular portion of Camrud is not considered or suggested; frangible members within the tubular portions is outside the purpose disclosed in Camrud to increase axial flexibility.

Likewise, Lock does not teach or suggest interconnected members which form at least one continuous pathway which extends around the longitudinal axis. Such a teaching is counter to the stated purpose of Lock for having a clam-shell like configuration. The stent in Lock is for use in children who have lumens that will yet grow in size. Therefore a stent that does not extend around the longitudinal axis is used because this provides for the growth of the lumen. Thus, combining the stent of Camrud with Lock is counter to the intended purpose of Lock and is inappropriate for a obviousness rejection.

Applicants believe that claim 30 is patentable in light of Camrud and Lock. Claims 35-37 are allowable for at least the reason that they claim dependence on an allowable base claim.

Applicants respectfully request that the 35 USC 103(a) rejection of claims 35-37 be withdrawn.

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Claims 39 and 40 were rejected under 35 USC 103(a) as being unpatentable over

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Mitsudou et al in view of US 5,591,223 to Lock et al. The Office Action acknowledged that Mitsudou does not teach pressures that frangible members can withstand before breaking.

Claims 39 and 40 are dependent upon claim 38. Claim 38 has been amended to recite that the interconnected struts include at least one temporary strut and permanent struts, the permanent struts fully defining at least one opening in the stent, the at least one temporary strut restraining self-expansion of at least one permanent strut about the at least one opening. Mitsudou does not teach self-expansion about an opening defined by permanent struts nor are these missing limitations taught or suggested in Lock. Lock is a sleeve stent in a claim shell configuration without temporary struts restraining permanent struts which define an opening. As such Lock does not teach self-expansion of the permanent struts upon breaking of a temporary strut.

It is believed that claim 38 is patentable over Mitsudou in light of Lock for at least the reasons given above. Claims 39 and 40 are believed to be allowable for at least the reason of claiming dependence upon an allowable base claim.

Applicants respectfully request that the 35 USC 103(a) rejection of claims 38 and 39 be withdrawn.

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Claim 45 was rejected under 35 USC 103(a) as being unpatentable over Mitsudou et al in view of Camrud et al. Claim 45 includes the stent of claim 38. Claim 38 is believed to be patentable over Mitsudou and Camrud for at least the reason that neither reference teaches nor suggests a stent having frangible members that when broken allow self-expansion. For at least this reason claim 45 is also patentable over the references.

Applicants respectfully request that the 35 USC 103(a) rejection of claim 45 be withdrawn.

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## CONCLUSION

In view of the foregoing it is believed that the present application, with pending claims 1-4, 6-15, 30, 33-42, 44, and 45, is in condition for allowance. Early action to that effect is earnestly solicited.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

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Brendan C. Babcock
Registration No.: 50705

6109 Blue Circle Drive, Suite 2000 Minnetonka, MN 55343-9185 Telephone: (952) 563-3000 Facsimile: (952) 563-3001

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